DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

January 19, 2007

Ref: **2007-DAL-WL-6**

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Dr. Marcus Christopher, MD and CEO
DreamWest Innovations, LLC
7742 Redbird Lane
San Antonio, Texas 78240

Dear Dr. Christopher:

During an inspection of your firm located at the above referenced address on November 1 through 9, 2006, investigators from the United States Food and Drug Administration (FDA) determined that your firm, a specification developer, manufactures and markets the SwiftGrip Rapid Intubation Kit which includes a cuffed endotracheal tube, a stylet of 14-French size, and a securing strap intended for oral or nasal intubation and for airway management. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. We received a response from your firm dated November 28, 2006, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. Your response briefly indicated that your firm has established a quality manual and was in the process of putting together all required information for your files. Your response is incomplete in that you have not identified and explained the specific procedures and records which will correct and verify the underlying GMP issues identified in the FDA 483 and this warning letter. A follow up inspection

will be required to assure that corrections are adequate.

The observed violations include, but are not limited to, the following:

1. Failure to adequately validate the manufacturing process with a high degree of assurance, approve, and document the results of the validation activities to ensure that product specifications can be consistently met, as required by 21 C.F.R. § 820.75(a). For example, your intubation kit is labeled as a sterile device. Your firm has no procedures and records proving that either your firm or your foreign contract manufacturer has adequately validated the [redacted] sterilization process.

2. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 C.F.R. § 820.30(a) through (j). For example, your firm has not established and approved a design plan, procedures and records for design inputs and outputs, design review, design verification and validation, design transfer, design changes, and a design history file for your intubation kits.

3. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria prior to releasing the devices for distribution, as required by 21 C.F.R. § 820.80(d), and failure to maintain acceptance records, as required by 21 C.F.R. § 820.80(e). For example, your firm has no procedures and records documenting how the devices were tested, inspected, or verified for conformance with approved acceptance criteria by both your foreign contract manufacturer and your firm prior to releasing the intubation kits in the United States.

4. Failure to establish and maintain a device master record (DMR) to include or refer to the location of device specifications, production process specifications, quality assurance procedures and specifications, packaging and labeling specifications, and failure to ensure that each DMR is prepared and approved in accordance with 21 C.F.R. § 820.40, as required by 21 C.F.R. § 820.181. For example, your firm has not established a device master record for your intubation kits.

5. Failure to establish and maintain procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 C.F.R. § 820.184. For example, your firm has not established

procedures specifying the specific production data (e.g., dates of manufacture, quantity manufactured, lot numbers, expiration dates, device labels and device labeling, and acceptance records which include documentation of sterility testing) to be included in the device history records.

6. Failure to establish and maintain adequate complaint handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit and to ensure that all the requirements of 21 C.F.R. § 820.198(a) through (e) are met. For example, your firm has not established a complaint handling procedure and a complaint file.

Our inspection also revealed that your devices are misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed to furnish any material or information respecting the device that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 C.F.R. Part 803 -- Medical Device Reporting (MDR) regulation. For example, your firm failed to establish and maintain adequate written MDR procedures, as required by 21 C.F.R. § 803.17, and maintain documentation and record keeping requirements for MDR event files, as required by 21 C.F.R. § 803.18.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Additionally, premarket approval applications for Class III devices to which the QS regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of these corrections. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Thao Ta, Compliance Officer, DAL-DO, Food and Drug Administration, HFR-SW140, 4040 N. Central Expressway, Suite 300, Dallas, TX 75240. If you have any questions about the contents of this letter, please contact Mr. Ta at 214-253-5217.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA-483, issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,

Michael A. Chappell
Dallas District Director

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